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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,463	06/18/2001	Max Diem	998-021	1246

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,463

Applicant(s)

DIEM ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-67 is/are pending in the application.
- 4a) Of the above claim(s) 43-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-38 is/are rejected.
- 7) ☒ Claim(s) 39-42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. This application contains claims directed to the following patentably distinct species of the claimed invention:
2. Ia. Claims 35-42, drawn to a method of separating and analyzing cells by IR, classified in class 436, subclass 63.
3. Ib. Claims 35-38, 43-46, drawn to a method of separating and analyzing cells by Raman, classified in class 436, subclass 63.
4. II. Claims 47-67, drawn to a method of locating and analyzing cells, classified in class 436, subclass 164.
5. Currently, no claim is generic to both primary species I and II. Claims 35-38 are generic to species I.
6. Applicant is advised that a reply to this requirement must include an identification of the species elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Newly submitted claims 43-67 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 43-46 are directed to a Raman analysis species not previously examined, and Claims 47-67 are directed to a locating and illuminating method species not requiring separating and statistical analysis of the previously examined species.

10. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-67 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

11. Claims 38-42 are objected to because of the following informalities: In claim 35, line 4, "of" belongs between "spectrum" and "cell"; line 7, "groups cells" should be "cells" because no plurality of groups has been recited. Appropriate correction is required.

12. The drawings are objected to because Figure 5 does not show labels indicating Figures 5a and 5b described in the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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13. The disclosure is objected to because of the following informalities: The disclosure describes Figures 5a and 5b, but Figure 5 is a single Figure without reference to Figures 5a and 5b.

Appropriate correction is required.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- a. Determining the scope and contents of the prior art.
- b. Ascertaining the differences between the prior art and the claims at issue.
- c. Resolving the level of ordinary skill in the pertinent art.
- d. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al in view of Kosaka and/or Ito et al.

18. Wang teaches a flow cytometry method of analyzing cells. Cells in a large group are passed through the cytometer where each cell is individually measured by fluorescence and IR (col. 5, lines 36-55). DNA can be detected and a plurality of dyes, stains and/or labels applied, including fluorescent dyes (col. 5, lines 5-35, especially 27-28 and 31-32). Histograms distinguishing G1, S and apoptosis phases based on fluorescence are obtained (col. 7, lines 30-40). The fluorescence measurements are an aspect of the vibrational spectrum in that there are plural different fluorescence properties measured (col. 5, lines 48-51) and fluorescence is a vibrational property (see Willard et al).

19. Wang fails to teach statistical analysis.

20. Kosaka teaches using statistical analysis of flow cytometry signals to classify cells (col. 6, lines 50-55).

21. Ito et al teach that flow cytometer methods conventionally use statistical analysis (col. 1, lines 13-23).

22. It would have been obvious to one of ordinary skill in the art at the time the invention was made to statistically analyze the data of Wang et al in order to classify the cells in the cytometer as taught by Kosaka and/or Ito. Note that fluorescence is used to

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distinguish cell populations as shown in the figures, as well as locate the cells, and fluorescence is a vibrational property as taught by Willard et al.

23. Applicant's arguments filed October 24, 2003 have been fully considered but they are not persuasive.

24. Applicant's arguments with respect to Cohenford are persuasive.

25. Applicant argues that Wang does not teach using an aspect of the vibrational spectrum to determine cell stage, but Wang uses fluorescence measurements to classify the cells by stage, and fluorescence is a vibrational property as explained above. Further, the fluorescence markers can be bound to DNA as noted above.

26. Claims 39-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

27. The following is a statement of reasons for the indication of allowable subject matter: Wang does not teach or suggest separating the cells, measuring an IR spectrum of the cells, using the IR spectrum to determine cell stage and statistically analyzing the characteristics of the cells.

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

29. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
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Jml
January 24, 2004